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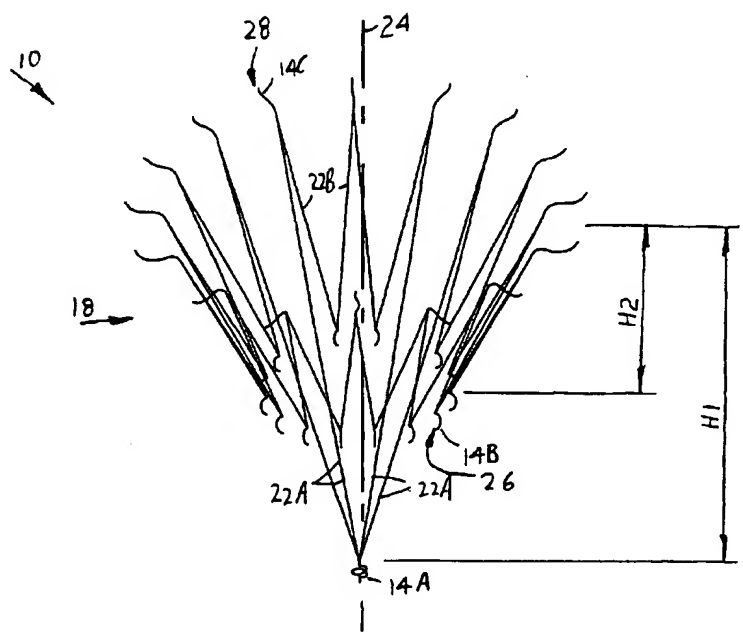

(57) **Abstract:** A method and a device (10) for improving cardiac function are provided. The device (10) is packaged in a collapsed state in an end of a catheter. Portions of a frame construction (12) of the device (10) spring outwardly when the catheter is withdrawn from the device (10). Anchoring formations (14) on the frame construction (12) secure the frame construction (12) to a myocardium of the heart. A membrane (16) secured to the frame construction (12) then forms a division between volumes of an endocardial cavity of the heart on opposing sides of the membrane (16).

WO 2004/012629 A1

A DEVICE FOR IMPROVING CARDIAC FUNCTION

BACKGROUND OF THE INVENTION

1). Field of the Invention

[0001] This invention relates to a method and device for improving cardiac function.

2). Discussion of Related Art

[0002] Congestive heart failure annually leads to millions of hospital visits internationally. Congestive heart failure is a description given to a myriad of symptoms that can be the result of the heart's inability to meet the body's demand for blood flow. In certain pathological conditions, the ventricles of the heart become ineffective in pumping the blood, causing a back-up of pressure in the vascular system behind the ventricle.

[0003] The reduced effectiveness of the heart is usually due to an enlargement of the heart. A myocardial ischaemia may, for example, cause a portion of a myocardium of the heart to lose its ability to contract. Prolonged ischemia can lead to infarction of a portion of the myocardium (heart muscle) wherein the heart muscle dies and becomes scar tissue. Once this tissue dies it no longer functions as a muscle and cannot contribute to the pumping action of the heart. When the heart tissue is no longer pumping effectively, that portion of the myocardium is said to be hypokinetic, meaning that it is less contractile than the uncompromised myocardial tissue. As this situation worsens, the local area of compromised myocardium may in fact bulge out as the heart contracts, further decreasing the heart's ability to move blood forward. When local wall motion moves in this way it is said to be dyskinetic. The dyskinetic portion of the myocardium may stretch and eventually form an aneurysmic bulge. Certain diseases may cause a global dilated myopathy, i.e., a general enlargement of the heart when this situation continues for an extended period

of time. As the heart begins to fail, the filling pressures increase, which stretches the ventricular chamber prior to contraction, greatly increasing the pressure (preload) to the heart. In response, the heart tissue remodels to accommodate the chronically increased filling pressures, further increasing the work that the now-compromised myocardium must perform. This vicious cycle of cardiac failure results in the symptoms of congestive heart failure such as shortness of breath on exertion, edema in the periphery, nocturnal dypsnia (a characteristic shortness of breath that occurs at night after going to bed), weight gain, and fatigue, to name a few. The enlargements increase stress on the myocardium. The stress increase requires a larger amount of oxygen supply, which can result in exhaustion of the myocardium leading to a reduced cardiac output of the heart.

SUMMARY OF THE INVENTION

[0004] This invention relates to a device for improving cardiac function. The device has a frame construction that is movable from a collapsed state, wherein the frame construction has a small cross-dimension to allow the frame construction to be fed through a tubular passage with a small diameter into the heart, to an expanded state wherein the frame construction, after leaving the tubular passage and having been located in an installed position in an endocardial cavity of the heart, has a cross-dimension substantially larger than the small diameter of the tubular passage and approximating a cross-dimension of the endocardial cavity where the frame construction is positioned. The device has at least one anchor formation connected to the frame construction, having at least one anchoring portion that is positioned and capable of anchoring to tissue of a myocardium of the heart, and so anchor the frame construction in the installed position to the myocardium. The device further has a membrane which is in a folded condition when being fed through the tubular passage, and in an unfolded condition after leaving the tubular passage, in the unfolded condition having an area substantially larger than a

cross-sectional area of the tubular passage, and being secured to the frame construction in a position to substantially form a division between volumes of the endocardial cavity on opposing sides of the membrane.

[0005] According to one aspect of the invention, at least two anchoring formations are connected to the frame construction, and are spaced from one another to allow for positioning of the frame construction at a select angle relative to the endocardial cavity.

[0006] According to another aspect of the invention, the frame construction is deformable into various non-circular shapes to allow for positioning thereof in endocardial cavities having differing non-circular shapes.

[0007] According to a further aspect of the invention, the frame construction includes a support frame next to and supporting the membrane, the support frame being sufficiently strong to support the membrane when a ventricular pressure acts on the membrane.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The invention is further described by way of examples with reference to the accompanying drawings, wherein:

[0009] Figure 1A is a perspective view of a main frame of a device, according to an embodiment of the invention, for improving cardiac function;

[0010] Figure 1B is a view similar to Figure 1A, illustrating the main frame in hidden lines and further illustrating in solid lines a support frame of the device mounted to the main frame;

[0011] Figure 1C is a top plan view illustrating a membrane of the device secured on top of the support frame;

[0012] Figure 2A is a cross-sectional side view of a heart, a catheter that is inserted into a left ventricle of the heart, and the device as it is packaged within an end of the catheter;

[0013] Figure 2B is a perspective view illustrating a device manipulating apparatus within the end of the catheter;

[0014] Figures 3A-3D illustrate how the device is secured to a myocardium of the heart;

[0015] Figures 4A-4B are graphs illustrating the pressures within the left atrium and the left ventricle, respectively;

[0016] Figures 5A-5C illustrate how the device can be mounted with the support frame to support the membrane in a different plane;

[0017] Figure 6 is a top plan view illustrating a larger device, according to another embodiment of the invention, mounted in a lower portion within a left ventricle of a heart;

[0018] Figures 7A-7B are perspective views from different sides, illustrating components of a device according to a further embodiment of the invention;

[0019] Figure 8 is a cross-sectional side view illustrating a sheet that is curved to substantially conform to an inner wall of a heart;

[0020] Figure 9 is a cross-sectional end view on 9-9 in Figure 8;

[0021] Figure 10 is a cross-sectional side view illustrating a device that is used for closing off a small ventricle of a heart; and

[0022] Figure 11 is a cross-sectional side view illustrating the same device as in Figure 10, used for closing off a large ventricle of a heart.

DETAILED DESCRIPTION OF THE INVENTION

[0023] Figures 1A, 1B, and 1C illustrate components of a device 10, according to an embodiment of the invention, for improving cardiac function. The device 10 includes a frame construction 12, a plurality of anchoring formations 14, and a membrane 16. The frame construction 12 includes a main frame 18 and a support frame 20 secured to the main frame 18. The membrane 16 is secured on top of the support frame 20.

[0024] As shown in Figure 1A, the main frame 18 includes a sequence or series of segments 22. Even segments of the series extend in an upward direction, and odd segments extend downward. The sequence formed by the segments 22 entirely surrounds a vertical axis 24. Movement of the segments

22 toward one another causes collapse of the main frame 18 toward the vertical axis 24. The frame construction 12 is made of a biocompatible wire-like shape-memory material, for example, nickel-titanium.

[0025] The anchoring formations 14 include a distal anchoring screw 14A, distal anchoring hooks 14B, and proximal anchoring hooks 14C. Two or more (in the present example, four) of the segments 22A are longer, and extend further down than other ones of the segments 22B. The segments 22A have their lower ends connected to one another, and the distal anchoring screw 14A is secured to the lower ends of the segments 22A. The segments 22A and 22B may be curved, as opposed to being straight as shown in the figures.

[0026] The distal anchoring hooks 14B are secured to lower ends of the segments 22B. Each distal anchoring hook 14B curves out and then down and is formed with a lower sharp end 26.

[0027] The proximal anchoring hooks 14C are secured to upper ends of the segments 22A and 22B. Each one of the proximal anchoring hooks 14C curves out and then up and terminates in an upper sharp end 28. The anchoring hooks 14B and 14C move together with the main frame 18 toward the vertical axis 24 when the main frame 18 is collapsed.

[0028] As shown in Figure 1C, the support frame 20 includes six (or more) elements 32, sequentially after one another and overlaying one another to form a six-pointed star. The elements 32 can pivot in a scissor-like manner relative to one another. Pivoting of the elements 32 relative to one another moves corners 34 of the star toward one another, while corners 36 on an opposing side of the star move toward one another. The support frame 20 then has an elongated configuration with the corners 36 at one end and the corners 34 at an opposing end.

[0029] Referring to Figure 1B, each corner 36 is positioned around and slidably secured to a respective one of the segments 22B. When the main frame 18 is collapsed, the corners 34 slide up the segments 22B to which they are secured, while the corners 36 remain at the bottom of the segments 22B to

which they are secured. When the main frame 18 is fully collapsed, the support frame 20 is in the form of an elongated arrangement extending along the vertical axis 24, with the corners 34 at the top and the corners 36 at the bottom.

[0030] Figure 1C also shows the membrane 16, in an unfolded condition, secured on the elements 32 of the support frame 20. An edge 40 of the membrane 16 is secured to the elements 32. Two of the elements 32 form a cross below a center of the membrane 16, and the other four elements 32 support the membrane 16 between the cross and the edge 40. Collapse of the support frame 20 folds the membrane 16 into an elongated folded arrangement extending along the elongated arrangement formed by the collapsed support frame 20. The membrane 16 is made of a biocompatible foldable material, for example Gore-Tex®, poly-ethylene terephthalate, or polypropylene mesh.

[0031] Figure 2A illustrates the device 10 that is inserted into a heart 42 by means of a catheter 44. The device 10 is collapsed and is inserted into an end of the catheter 44. The axis 24, shown vertically in Figures 1A and 1B, now extends along an axis of an elongated tubular passage 46 in the catheter 44. The device 10 is packaged with the distal anchoring screw 14A protruding from the end of the catheter 44. The catheter 44 is non-invasively steered through the aorta 48 and the aortic valve (not shown) into the left ventricle 52A of the heart 42. The other chambers of the heart 42 are the right ventricle 52B, the left atrium 50A, and the right atrium 50B.

[0032] As shown in Figure 2B, a device manipulating apparatus 54 is disposed within the catheter 44. The apparatus 54 includes an elongated manipulator 56, a rotator piece 58, and a support piece 60. Only a distal portion of the elongated manipulator 56 is shown. A handle (not shown) is attached to a proximal portion of the elongated manipulator 56. The elongated manipulator 56 can bend to conform to the curved or bent shape of the catheter 44, but is relatively rigid against a torque about an elongated axis thereof. The rotator piece 58 is secured to an end of the elongated manipulator 56, and the support piece 60 is secured to the elongated manipulator 56 slightly proximal to the

rotator piece 58. The rotator piece 58 has an internal device engaging formation 62. The device 10 is inserted into the formation 62 until proximal surfaces of the device 10 contact the support piece 60. The formation 62 conforms to an outer shape of the device 10, so that the device 10 rotates together with the rotator piece 58 when the rotator piece 58 is rotated by the elongated manipulator 56. The device 10 may be fed out of an end of the catheter 44 by the support piece 60 when the elongated manipulator 56 is advanced in an elongated direction of the catheter 44. The support piece 60 also prevents movement of the device 10 in an opposite direction into the catheter 44.

[0033] Reference is now made to Figure 3A. The myocardium 74 of the heart has formed an aneurysmic formation or bulge 76 out of the left ventricle 52A. A previous infarction, or cessation of blood supply, to the portion of the myocardium 74 now forming the bulge 76. Continuous exposure of the dyskinetic portion of the myocardium 74 to high pressures in the left ventricle 52A has caused the aneurysmic bulge 76.

[0034] The catheter 44 is steered so that the distal anchoring screw 14A contacts a base of the bulge 76. The catheter 44 is then rotated so that the distal anchoring screw 14A screws into the myocardium 74 at a target site the base of the bulge 76.

[0035] As shown in Figure 3B, the catheter 44 is then retracted over the device 10, with the distal anchoring screw 14A anchoring the frame construction 12 to the myocardium 74 at the base of the bulge 76. The distal anchoring hooks 14B leave the catheter 44 as the catheter 44 is retracted, before the remainder of the device 10, and bend outwardly under spring action.

[0036] As shown in Figure 3C, further withdrawal of the catheter 44 from the segments 22B causes the segments 22B to spring outwardly, and the distal anchoring hooks 14B to come into contact with the myocardium 74. The support frame 20 pivots away from its alignment with the center axis of the elongated tubular passage 46, and the proximal anchoring hooks 14C are at this

stage still located within the elongated tubular passage 46.

[0037] As shown in Figure 3D, the catheter 44 is subsequently withdrawn from proximal anchoring hooks 14C. Proximal portions of the segments 22A and 22B spring outwardly after the proximal anchoring hooks 14C leave the tubular passage 46, so that the proximal anchoring hooks 14C move outwardly into contact with the myocardium 74. A proximal portion of each segment 22A or 22B pivots relative to a distal portion thereof. Pivoting of the segments 22B rotates the lower sharp ends 26 of the distal anchoring hooks 14B into the myocardium 74. Embedding of the distal anchoring hooks 14B into the myocardium 74 anchors the segments 22B to the myocardium 74. Beating of the heart 42 causes relative movement between the myocardium 74 and proximal anchoring hooks 14C, so that the upper sharp ends 28 may also penetrate the myocardium 74. The proximal anchoring hooks 14C are thereby also embedded into the myocardium 74, and anchor proximal portions of the segments 22A and 22B to the myocardium 74. Each segment 22A or 22B is near the myocardium 74 at all locations along the length of the respective segment 22A or 22B, and is anchored to the myocardium 74 through the anchoring formations 14.

[0038] The corners 34 of the support frame 20 slide along the segments 22B to which they are secured when the segments 22B rotate outwardly relative to one another. When comparing Figure 3D with Figure 3C, it can be seen that the support frame 20 is in a plane which is substantially at right angles with respect to the axis of the elongated tubular passage 46. The membrane 16 (Figure 1C) unfolds and is supported on top of the support frame 20. The membrane 16 forms a division between the aneurysmic bulge 76 and a remainder of the left ventricle 52A.

[0039] After the device 10 is installed, the aneurysmic bulge 76, having been segregated from the remainder of the left ventricle 52A, eventually clots off behind the membrane 16, thereby effectively reducing the internal volume in the left ventricle 52A. Stretching of the portion of the myocardium 74 forming

the aneurysmic bulge 76 is also effectively eliminated. By blocking off a portion of the left ventricle 52A not contributing to pumping during a systolic portion of a pump cycle, properly functioning portions of the myocardium 74 can contract normally and use up a normal amount of oxygen. By reducing the amount of oxygen uptake during a given period of time, properly functioning portions of the myocardium 74 are not exhausted and can continue to function properly. Cardiac output increases and the likelihood of congestive heart failure is reduced.

[0040] Figures 4A and 4B illustrate pressures within the left atrium 50 and the left ventricle 52A, respectively, of a healthy human being. It can be seen that the peak left ventricular pressure, i.e., the pressure in the left ventricle 52A during the systolic portion, reaches approximately 120 mm Hg. This pressure acts directly on the membrane 16. It can be assumed that the pressure on an opposing side of the membrane 16, i.e., the side of the aneurysmic bulge 76, is close to zero. The support frame 20 supports the sheet 16 at a sufficient number of locations and is sufficiently strong to prevent the membrane 16 from collapsing during peak systolic pressure. An peak pressure in the region of 50 to 60 mm Hg for a sustained period of a few hours is generally regarded as being incompatible with life.

[0041] In the given example, there are a total of 31 anchoring formations 14, including the distal anchoring screw 14A, 14 distal anchoring hooks 14B, and 16 proximal anchoring hooks 14C. The large number of anchoring formations 14 ensure proper anchoring to the myocardium 74. The large number of anchoring formations 14 also allows for positioning of the membrane 16 at a select location within the left ventricle 52A and at a select angle and within a select plane relative to the myocardium 74. The anchoring formations 14, and in particular the anchoring hooks 14B and 14C, their shape, orientation, and placement, are thus uniquely suited for anchoring of the frame construction 12, especially when compared with other anchoring formations such as pins, clamps, staples, screws, and surgical thread. What should also be noted is that

the anchoring formations 14 penetrate through only a portion of the myocardium 74, and thus do not damage the pericardium. What should further be noted is that none of the anchoring formations 14 or other components of the device 10 can bump against the myocardium 74, to avoid electrostimulation of the myocardium 74 that can lead to arrhythmias.

[0042] Figures 5A, 5B, and 5C illustrate one manner in which the support frame 20 and the membrane 16 can be positioned at a select angle relative to the myocardium 74. When comparing Figure 5A with Figure 3C, it can be seen that the catheter 44 is positioned closer to a right side (as viewed) of the myocardium 74. The distal anchoring hooks 14B on the right engage with the myocardium 74 before the distal anchoring hooks 14B on the left engage with the myocardium 74. Further withdrawal of the catheter 44, as shown in Figure 5B, results in engagement of the distal anchoring hooks 14B on the left with the myocardium 74 at a location which is displaced by an offset distance 80 in a direction of an axis of the elongated tubular passage 46. When comparing Figure 5C with Figure 5B, it can be seen that, due to the offset distance 80, the support frame 20 is eventually at an angle of approximately 60° relative to the axis of the elongated tubular passage 46. Although not blocking a mouth of the aneurysmic bulge 76, this serves to illustrate that the membrane 16 can be positioned in different select planes, as may be required, due to the flexibility of the frame construction 12 and various virtual triangles that are formed by connecting locations where the anchoring formations 14 anchor to the myocardium 74.

[0043] Referring again to Figures 1A, 1C, and 3A, the main frame 18 has a vertical height H1, a height from the distal anchoring hooks 14B to the proximal anchoring hooks 14C H2, the membrane 16 has a width W, and the elongated tubular passage 46 has a diameter D. These dimensions can be modified according to requirement, and the following table lists a number of examples:

H1	H2	W	D
6 cm	3 cm	2.5 cm	1 cm
7 cm	4 cm	3 cm	1.2 cm
8 cm	5 cm	4 cm	1.5 cm
8.5 cm	5.5 cm	5 cm	2 cm
9.5 cm	6 cm	6 cm	2.2 cm
9.5 cm	8 cm	7 cm	2.6 cm

[0044] The first row in the table lists the dimensions for the device 10 hereinbefore described which is used for blocking a relatively small aneurysmic bulge 76. Larger aneurysmic bulges can be blocked using slightly larger devices. As mentioned, certain diseases may cause general enlargement of endocardial cavities of a heart without necessarily creating a specific identifiable bulge. Larger devices can be used to block portions of these enlarged endocardial cavities. In such cases, it may also be possible to use two devices in a side-by-side arrangement or with their membranes overlapping one another.

[0045] Figure 6 illustrates one such a larger device 110 that is inserted in the bottom of the left ventricle 152 of a heart 114. The main frame (not shown) of the device 110 is formed into a non-circular shape, so that an outline formed by corners 134 and 136 of a support frame of the device define a non-circular shape. A membrane 116 mounted on top of the support frame also defines a non-circular shape. The shape of the membrane 116 conforms approximately to a non-circular D-shape of the left ventricle 152 at a height where the membrane 116 is positioned. The same device 110 can be deformed into various different shapes, according to requirement.

[0046] Figures 7A and 7B illustrate a frame construction 212 and anchoring formations 214 of a device according to an alternative embodiment of the invention. The frame construction 212 includes a main frame 218 and a support frame 220. The main frame 218 has a plurality of segments 222 having distal ends connected to one another at a common location 224. Proximal portions of the segments 222 can collapse toward one another and spring

outwardly away from one another. The anchoring formations 214 include a distal anchoring screw 214A secured at the common location 224, and proximal anchoring hooks 214B on proximal ends of the segments 222. The support frame 220 includes a plurality of elements 232. The elements 232 have ends that are pivotally connected to one another at a common location 254. An opposing end of each element 232 is slidably secured to a respective one of the segments 222. The manner in which the segments 222 of the main frame 218 collapse is simultaneously replicated by the manner in which the elements 232 of the support frame 220 collapse. In use, the distal anchoring screw 214A is first screwed into a myocardium. A catheter is then withdrawn from the frame construction 212. Once the catheter is entirely removed from the frame construction 212, the proximal anchoring hooks 214B spring outwardly and embed themselves into the myocardium. The support frame 220 simultaneously moves from its collapsed condition into its expanded condition. A membrane (not shown) is secured to, unfolded by, and supported by the support frame 220.

[0047] The support frame of a device may be shaped so that a membrane attached to the support frame has a desired shape. Figures 8 and 9, for example, illustrate a membrane 316 that conforms approximately to a shape defined by an anterior wall 320 and a septum 322 of a heart. As shown in Figure 8, the membrane 316 has a portion on the left having a radius R1 and a portion on the right having a radius R2 which is a multiple of the radius R1. The sheet 316 material may be formed to have more than two radii of curvature. Referring to Figure 9, it can be seen that the membrane 316 is curved also when viewed on 9-9 in Figure 8. The curved shape of the membrane 316 allows the membrane 316 to block off larger portions of the anterior wall 320 and the septum 322 without reducing the internal volume of the left ventricle by too great a degree.

[0048] It may also be possible to use the same device to block off either large or small cavities. Figures 10 and 11 illustrate the same device 410 used for

closing off a small ventricle 412 and a large ventricle 414, respectively. As in, for example, the embodiment described with reference to Figures 7A and 7B, the device 410 has a frame construction 416 that can spring outwardly, and a membrane 418 secured and expanded by the frame construction 416. The frame construction 416 springs out more in Figure 11 than in Figure 10, and the membrane 416 is accordingly unfolded into a larger cross-sectional shape.

[0049] The support frame and anchoring formations of, for example, the device illustrated in Figure 1A may be used for other purposes instead of or in addition to supporting a membrane as described. The frame construction 18 provides an electrically conductive path that can be used for left ventricular pacing. For example, one of the proximal anchoring hooks 14C may engage with and be sufficiently long to penetrate from a left ventricle through a septum into a right ventricle of a heart. A terminal of a pacemaker can then be inserted into the right ventricle and connected to the hook that penetrates through the septum. Electric current can conduct between the terminal of the pacemaker through the main frame 18 to other ones of the anchoring formations 14 connected to the myocardium of the left ventricle. The frame construction 12 also provides a strong support for mounting components that can be used for other purposes, such as an annulus component that can be positioned around the mitral valve, or a component that is used for reshaping a papillary muscle. The device 10 can also be used for delivering of drugs, proteins, stem cells, etc. to the heart.

[0050] While certain exemplary embodiments have been described and shown in the accompanying drawings, it is to be understood that such embodiments are merely illustrative and not restrictive of the current invention, and that this invention is not restricted to the specific constructions and arrangements shown and described since modifications may occur to those ordinarily skilled in the art.

CLAIMS

What is claimed:

1. A device for improving cardiac function, comprising:

a frame construction that is movable from a collapsed state, wherein the frame construction has a small cross-dimension to allow the frame construction to be fed through a tubular passage with a small diameter into a heart, to an expanded state wherein the frame construction, after leaving the tubular passage and having been located in an installed position in an endocardial cavity of the heart, has a cross-dimension substantially larger than the small diameter of the tubular passage and approximating a cross-dimension of the endocardial cavity where the frame construction is positioned;

at least two anchor formations connected to the frame construction, each anchor formation having at least one anchoring portion that is positioned and capable of anchoring to tissue of a myocardium of the heart, and so anchor the frame construction in the installed position to the myocardium, the anchoring portions being spaced from one another to allow for positioning of the frame construction at a select angle relative to the endocardial cavity; and

a membrane being in a folded condition while being fed through the tubular passage, and in an unfolded condition after leaving the tubular passage, in the unfolded condition having an area substantially larger than a cross-sectional area of the tubular passage and being secured to the frame construction in a position to substantially form a division between volumes of the endocardial cavity on opposing sides of the membrane.

2. The device of claim 1, comprising a third anchor formation, anchor portions of the anchor formations being positioned at corners of a triangle to allow for positioning of the frame construction with the membrane in a select plane relative to the endocardial cavity.

3. The device of claim 1, wherein the anchoring portions have sharp ends that penetrate the myocardium.

4. The device of claim 3, wherein at least some of the anchoring formations are anchoring hooks.

5. The device of claim 4, wherein at least some of the anchoring hooks are distal anchoring hooks on a distal portion of the frame construction and rotate into the myocardium while a catheter forming the tubular passage is withdrawn off the frame construction.

6. The device of claim 5, wherein partial withdrawal of the catheter off a distal portion of the frame construction causes expansion of the distal portion of the frame construction and movement of the distal anchoring hooks away from a center line of the tubular passage, so that the sharp ends of the distal anchoring hooks move into contact with the myocardium, and further withdrawal of the catheter off the frame construction causes rotation of the distal anchoring hooks into the myocardium.

7. The device of claim 6, wherein a proximal portion of the frame construction expands after leaving the tubular passage, expansion of the proximal portion of the frame construction causing rotation of the distal anchoring hooks into the myocardium.

8. The device of claim 4, wherein at least some of the anchoring hooks are proximal anchoring hooks on a proximal portion of the frame construction, the proximal portion of the frame construction expanding after leaving the tubular passage, expansion of the proximal portion of the frame construction causing movement of the proximal anchoring hooks away from a center line of the tubular passage so that the proximal anchoring hooks move into contact with

the myocardium.

9. The device of claim 1, wherein the frame construction includes a main frame surrounding a vertical axis and comprising a sequence of sections that alternate in upward and downward directions, expansion of the frame construction moving the sections apart.

10. The device of claim 9, wherein, when viewed from above, the frame construction is deformable into various non-circular shapes to allow for positioning thereof in endocardial cavities having differing non-circular shapes.

11. The device of claim 1, wherein, when viewed from above, the frame construction surrounds a vertical axis and is deformable into various non-circular shapes to allow for positioning thereof in endocardial cavities having differing non-circular shapes.

12. The device of claim 1, wherein the frame construction includes a main frame that expands away from a center line of the tubular passage, and a support frame which, when the main frame is in the expanded state, is mounted to the main frame within an opening defined by the main frame, the support frame supporting the membrane.

13. The device of claim 12, wherein the support frame is sufficiently strong to support the membrane when a ventricular pressure acts on the membrane.

14. The device of claim 13, wherein the ventricular pressure is at least 60 mm Hg.

15. The device of claim 12, wherein the support frame, when the main frame is in the collapsed state, is collapsed into an elongated arrangement extending

along a length of the tubular passage.

16. The device of claim 15, wherein the support frame has at least two elements that pivot relative to one another in a scissor-like manner.

17. The device of claim 1, wherein the membrane is within the frame construction when the frame construction is in the collapsed state.

18. The device of claim 1, wherein the membrane is at least 3 cm in diameter.

19. A device for improving cardiac function, comprising:

a membrane that is movable from a folded condition, wherein the membrane can be fed through a tubular passage having a small cross-sectional area, to an unfolded condition after leaving the tubular passage, in the unfolded condition the membrane having an area substantially larger than the cross-sectional area of the tubular passage and being located in a position wherein the membrane forms a division between volumes of an endocardial cavity on opposing sides of the membrane;

a frame construction that is movable from a collapsed state, wherein the frame construction has a small cross-dimension to allow the frame construction to be fed through a tubular passage with a small diameter into the heart, to an expanded state wherein the frame construction, after leaving the tubular passage and having been located in an installed position in an endocardial cavity of the heart, has a cross-dimension substantially larger than the small diameter of the tubular passage and approximating a cross-dimension of the endocardial cavity where the frame construction is positioned, the frame construction being deformable into various non-circular shapes to allow for positioning thereof in endocardial cavities having differing non-circular shapes;

at least one anchor formation connected to the frame construction, the anchor formation having at least one anchoring portion that is positioned and

capable of anchoring to tissue of a myocardium of the heart, and so anchor the frame construction in the installed position to the myocardium.

20. The device of claim 19, wherein the frame construction includes a main frame surrounding a vertical axis and comprising a sequence of sections that alternate in upward and downward directions, expansion of the frame construction moving the sections apart.

21. A device for improving cardiac function, comprising:

a membrane that is movable from a folded condition, wherein the membrane can be fed through a tubular passage having a small cross-sectional area, to an unfolded condition after leaving the tubular passage, in the unfolded condition the membrane having an area substantially larger than the cross-sectional area of the tubular passage and being located in a position wherein the membrane forms a division between volumes of a ventricular cavity of a heart on opposing sides of the membrane;

a frame construction that is movable from a collapsed state, wherein the frame construction has a small cross-dimension to allow the frame construction to be fed through a tubular passage with a small diameter into the heart, to an expanded state wherein the frame construction, after leaving the tubular passage and having been located in an installed position in the ventricular cavity, has a cross-dimension substantially larger than the small diameter of the tubular passage and approximating a cross-dimension of the ventricular cavity where the frame construction is positioned, the frame construction including a support frame next to and supporting the membrane, the support frame being sufficiently strong to support the membrane when a ventricular pressure of a healthy human being acts on the membrane; and

at least one anchor formation connected to the frame construction, the anchor formation having at least one anchoring portion that is positioned and capable of anchoring to tissue of a myocardium of the heart, and so anchor the

frame construction in the installed position to the myocardium.

22. The device of claim 21, wherein the ventricular pressure is at least 60 mm Hg.

23. The device of claim 21, wherein the support frame, when the main frame is in the collapsed state, is collapsed into an elongated arrangement extending along a length of the tubular passage.

24. The device of claim 23, wherein the support frame has at least two elements that pivot relative to one another in a scissor-like manner.

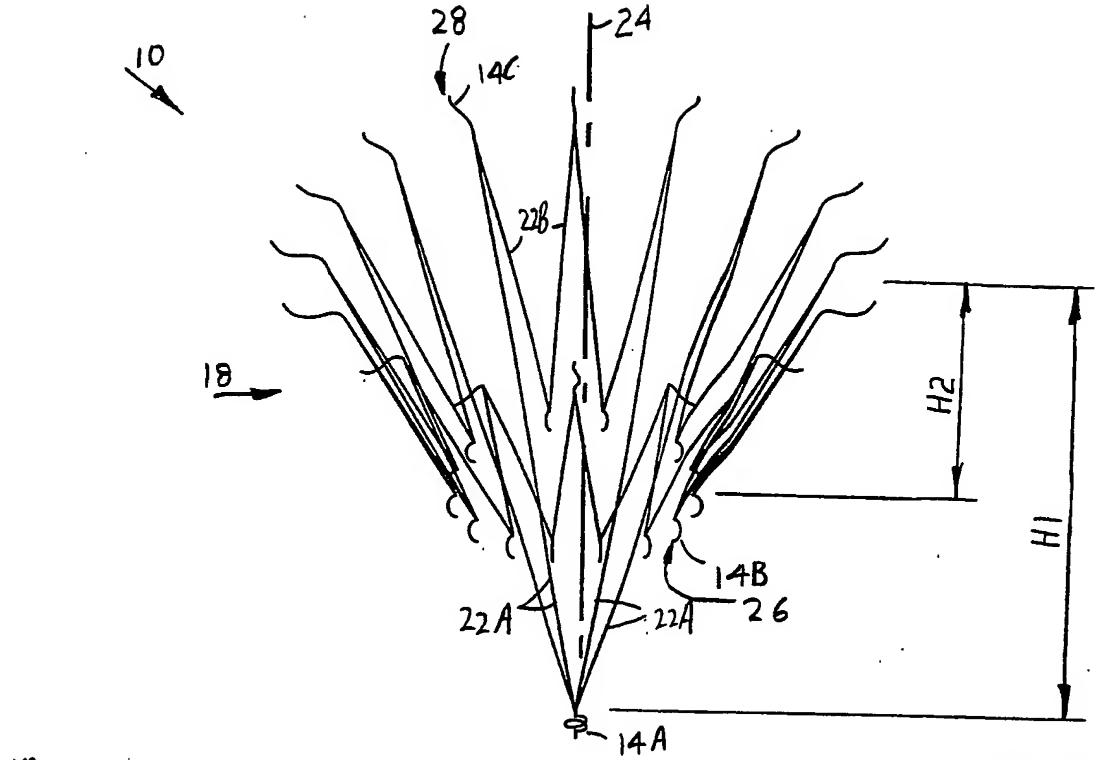
10
28
24
14C
22B
18
H2
H1
14B
22A
22A
26
14A

FIG 1A

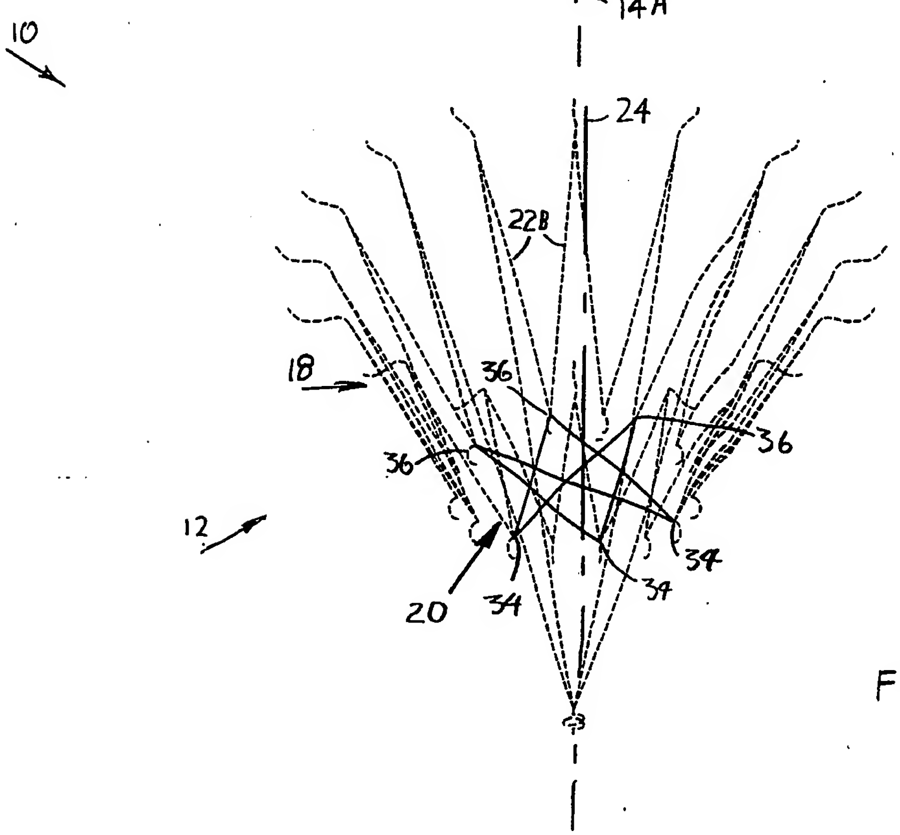
10
24
22B
18
36
36
36
12
20
34
34
34

FIG 1B

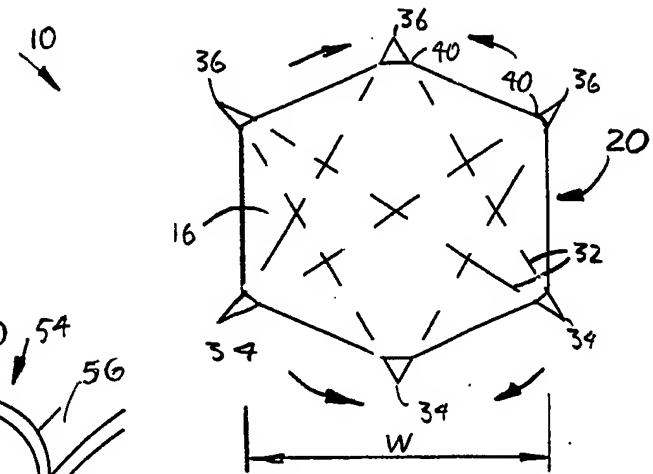

FIG 1C

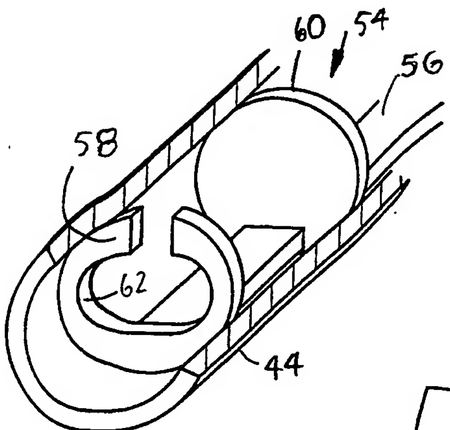

FIG 2B

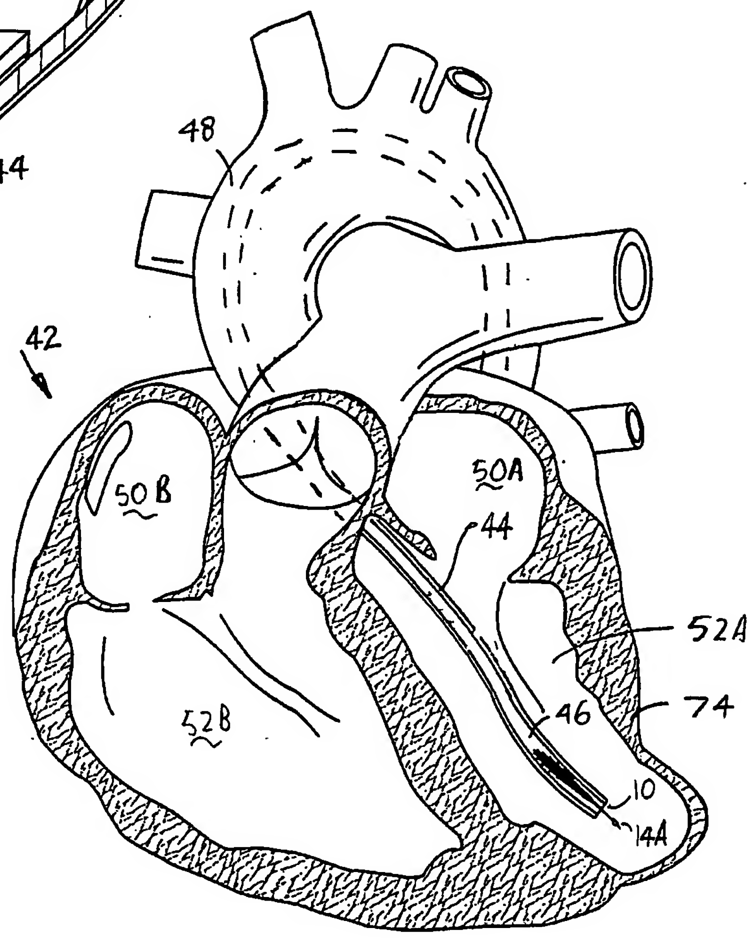

FIG 2A

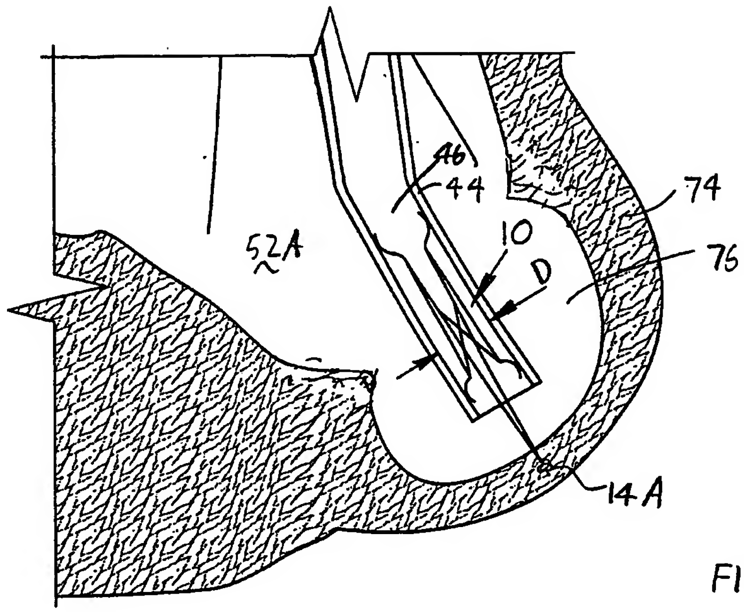

FIG 3A

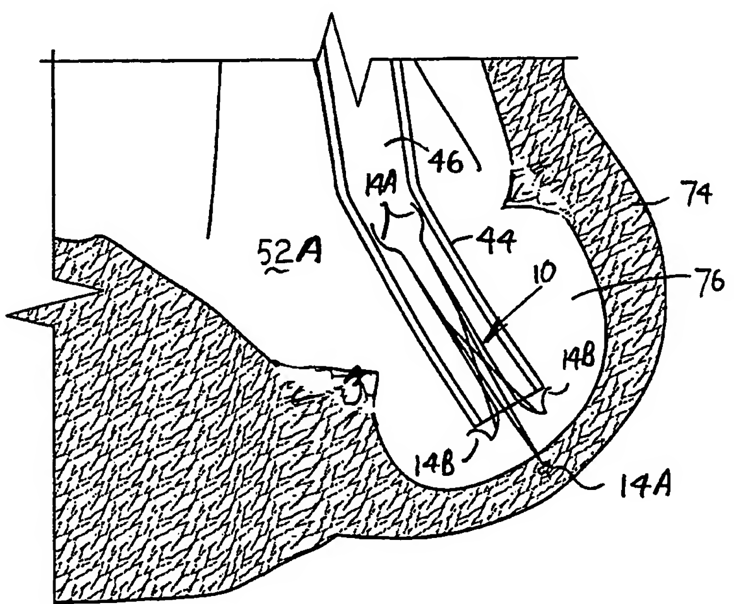

FIG 3B

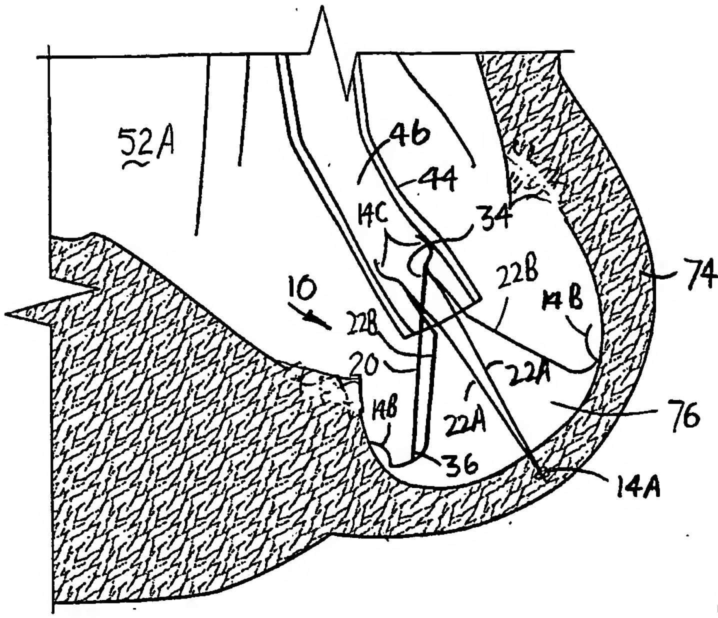
52A
46
44
14C
34
10
22B
22B
14B
20
22A
22A
76
14B
36
14A
74

FIG 3C

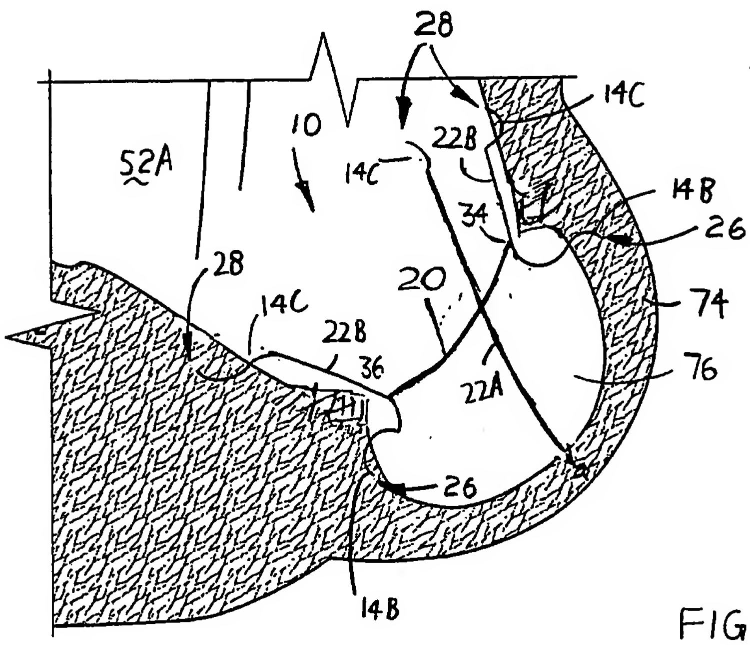
28
14C
10
52A
14C
22B
14B
34
26
74
28
20
14C
22B
36
22A
76
26
14B

FIG 3D

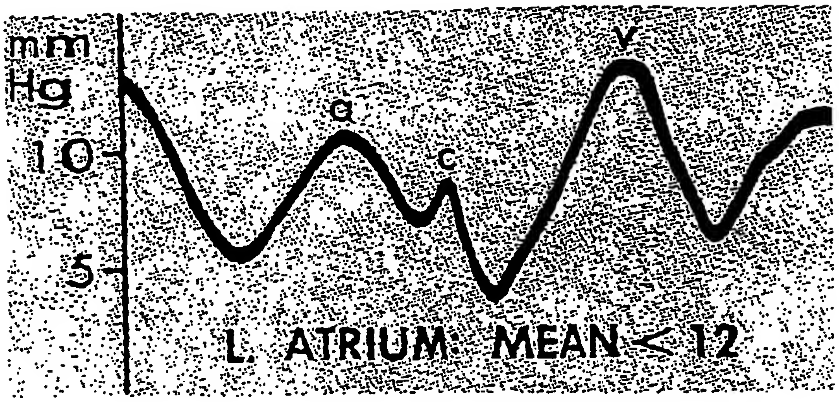
mm Hg
10
5
a
c
v
L. ATRIUM: MEAN < 12

FIG 4A

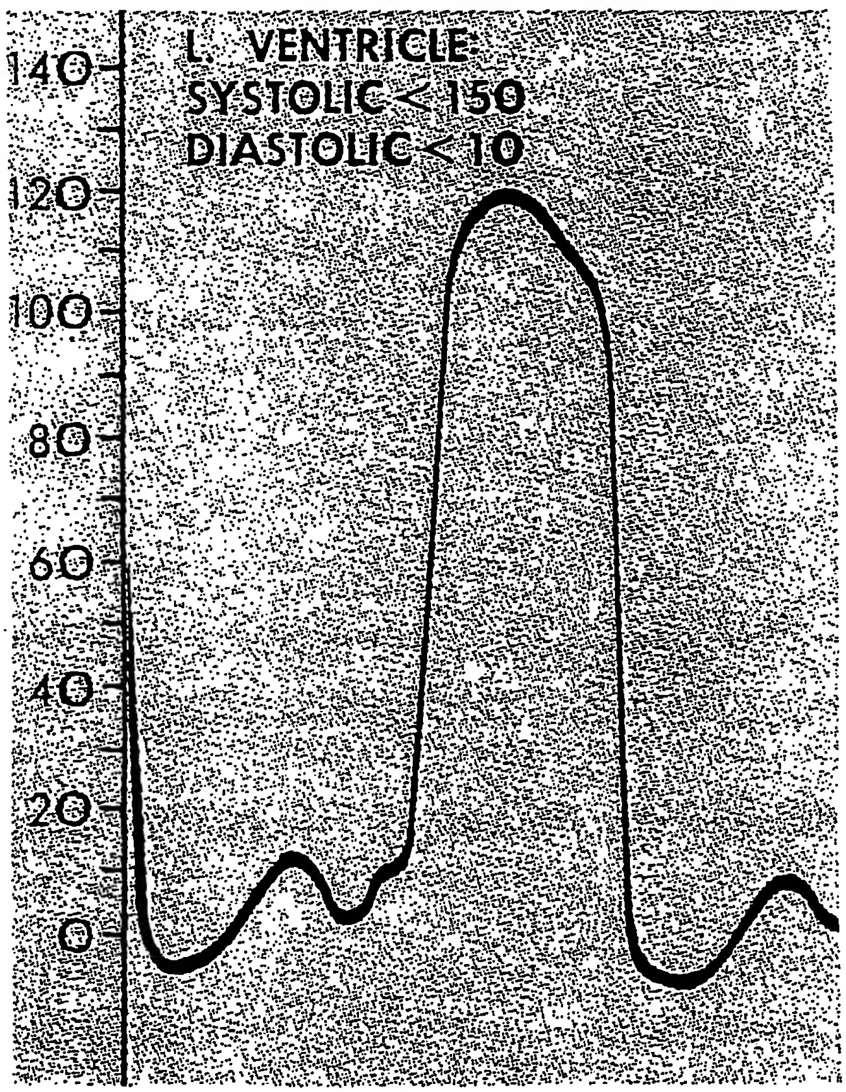
140
120
100
80
60
40
20
0
L. VENTRICLE:
SYSTOLIC < 150
DIASTOLIC < 10

FIG 4B

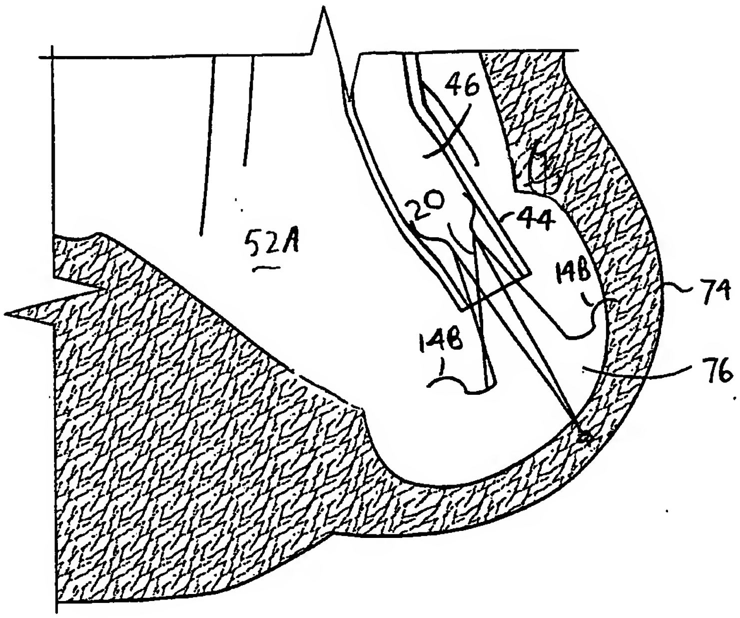

FIG 5A

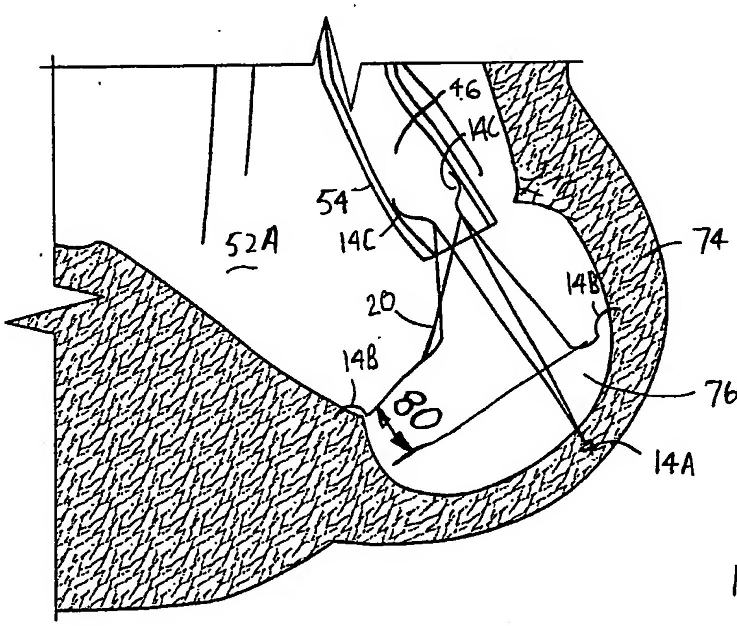

FIG 5B

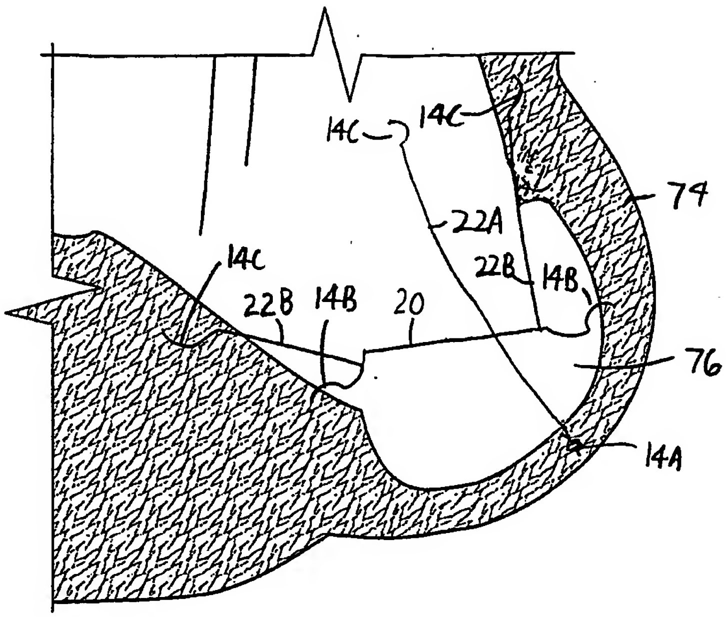
14C
14C
74
22A
14C
22B
14B
22B
14B
20
76
14A

FIG 5C

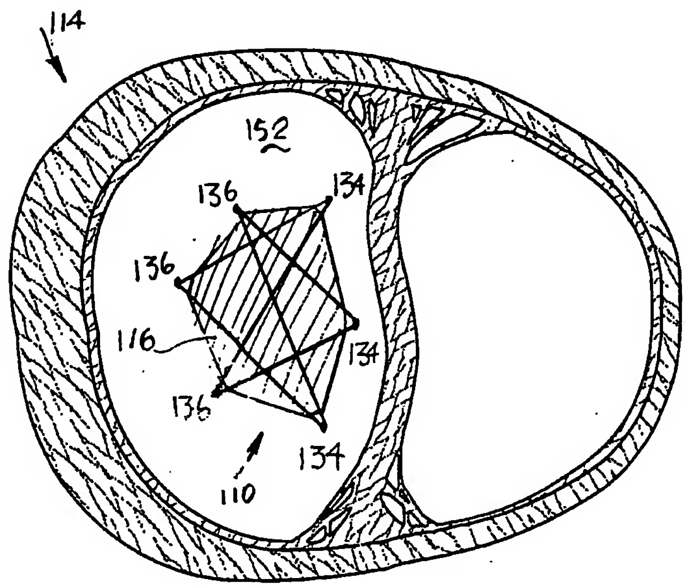
114
152
136
134
136
116
134
136
134
110

FIG 6

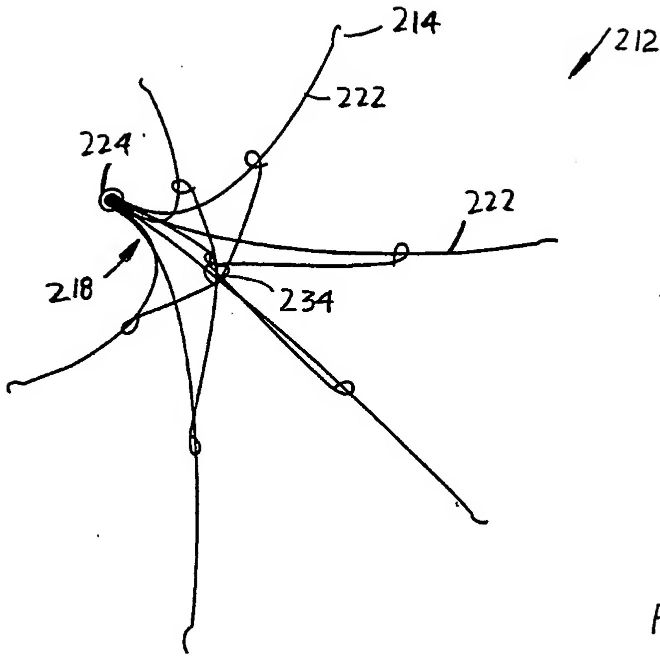
214
212
222
224
222
218
234

FIG 7A

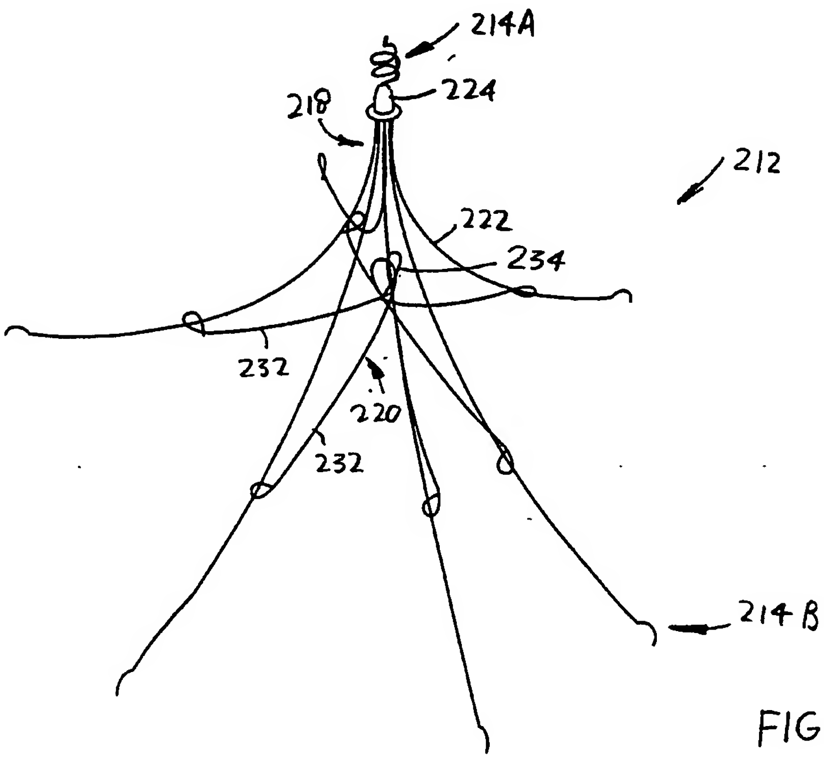
214A
224
218
212
222
234
232
220
232
214 B

FIG 7B

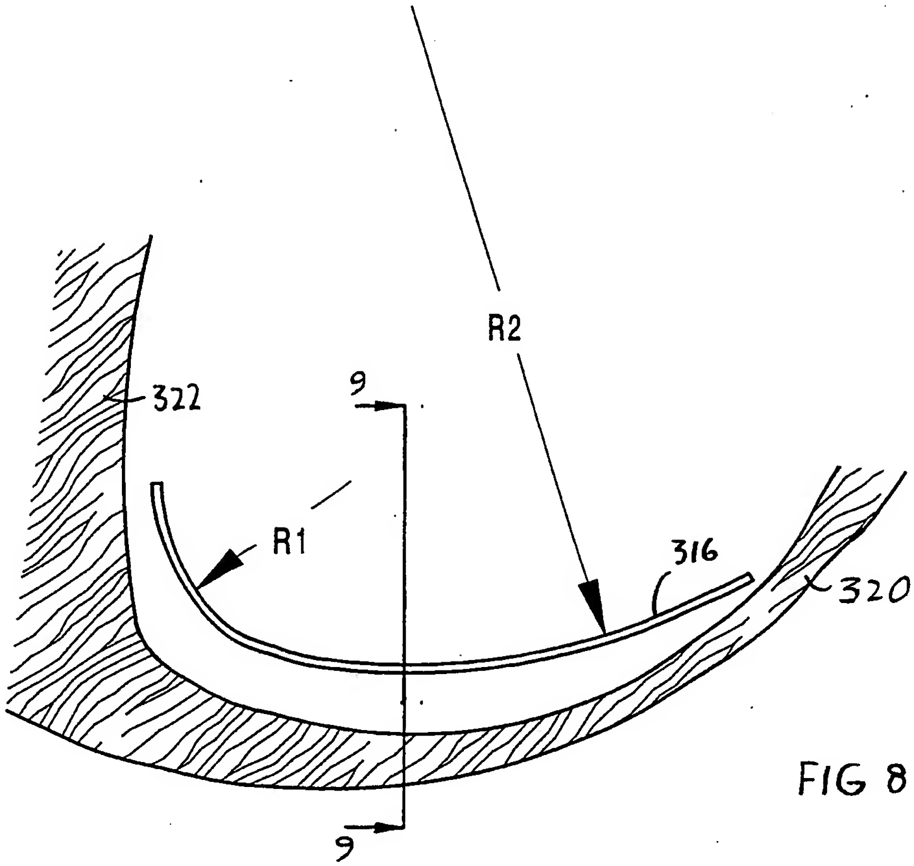

FIG 8

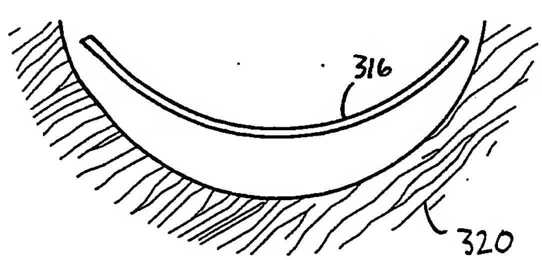

FIG 9

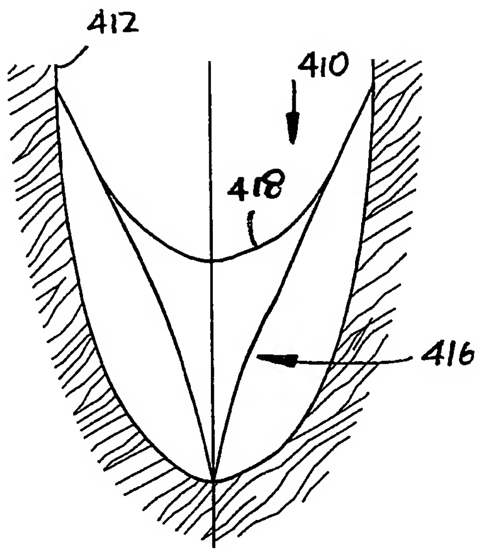

FIG 10

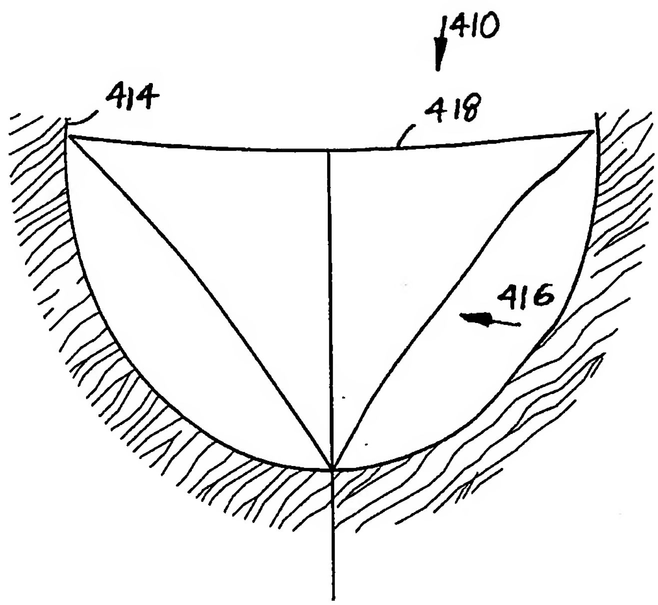

FIG 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/24620

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/04
US CL : 623/23.64

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/1,23.64;606/200,213;

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3,874,388 A (King et al.) 01 April 1975 (01.04.1975), col. 6, lines 22-25, and lines 49-58, Fig. 7, Fig. 9A-9F, Fig. 2A (83), 3A (93), Fig. 12B, Fig. 15A.	1-6,8,15-21,23-24
A	US 5,634,942 A (Chevillon et al.) 03 June 1997 (03.05.1997), Fig. 11.	9-12
A	US 6,093,199 A (Brown et al.) 25 July 2000 (25.07.2000), entire publication.	1-24

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 October 2002 (29.10.2002)	04 DEC 2002

Name and mailing address of the ISA/US	Authorized officer
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